

Claims

- 1) A method for the production of a biologically active prosthetic device for the reconstruction of bone tissue, comprising the following steps:
CAT (Computerised Axial Tomography) scan of the patient and obtaining a three-dimensional electronic model (1) of the part of the bone and of a bone defect (2) to be reconstructed;
creation through prototyping of a prototype resin model (3) of the area of the patient's bone involved, for example using the three-dimensional stereolithographic technique;
forming of a model (4), for example by means of "slip casting" forming, of the patient's bone defect (2) to be reconstructed;
construction of a negative mould (5), for example using "slip casting" forming, of the patient's bone defect (2) to be reconstructed;
production of a ready sintered ceramic semi-finished product with controlled and interconnected porosity (30 - 90%) with pore dimensions in the 0.1 - 125 microns and 125 - 2500 microns range;

the method being characterised in that the semi-finished product obtained by the previous step has dimensions and shape nearing in excess the ones of the bone defect (2); and in that it comprises step of mechanical processing and manual finishing of the sintered semi-finished product to obtain the precise dimensions and shape of the bone defect (2).

- 2) The method for the production of a prosthetic device according to claim 1, characterised in that the mechanical processing and manual finishing are carried out by removing excess material using diamond milling cutters which turn at high speed.
- 3) The method for the production of a prosthetic device according to claim 1 or 2, characterised in that the negative mould (5) of the patient's bone defect comprises means (8) able to detect any points of contact between the semi-finished product and the mould (5).
- 4) The method for the production of a prosthetic device according to claim 3, characterised in that the means (8) able to detect any points of contact

between the semi-finished product and the mould (5) comprise a coating of tracing paper which can be coloured at points of contact.

- 5) The method for the production of a prosthetic device according to any of the foregoing claims, characterised in that the material used to make it is a Ca/P compound-based biologically active ceramic material.
- 6) The method for the production of a prosthetic device according to any of the foregoing claims, characterised in that the material used to make the device is a ceramic material selected from the group consisting of: stoichiometric hydroxyapatite; non-stoichiometric hydroxyapatite: carbonated hydroxyapatite (mainly of type B); hydroxyapatite enriched with magnesium or fluoride or with strontium or sodium; carbonated hydroxyapatite enriched with magnesium; hydroxyapatite/ β tricalcium phosphate in proportions of 50% - 50%, 70% - 30%, 30% - 70%; alpha-tricalcium phosphate (α TCP); beta-tricalcium phosphate (β TCP); mixtures of alpha-tricalcium phosphate (α TCP) and beta-tricalcium phosphate (β TCP), the hydroxyapatite-

based material which forms the subject matter of patent IT-1 307 292, and the hydroxyapatite-based material which forms the subject matter of patent EP-1 411 035 (and the corresponding application for an Italian patent BO2002A000650).

- 7) The method for the production of a prosthetic device according to any of the foregoing claims, characterised in that it comprises a step of final checking of the prosthetic device component, in terms of dimensions and shape, the check being carried out on the resin model of the area of the patient's bone involved and using the negative mould (6 or 7).
- 8) A biologically active prosthetic device for the reconstruction of bone tissue obtained according to the method in any of the foregoing claims, characterised in that the shape and dimensions derive from a model of the area of the patient's bone involved, said model being obtained using rapid prototyping technology, for example stereolithography; and also characterised in that it has a structure with predetermined and interconnected porosity (30 - 90%) with bimodal

distribution of the dimensions of the pores in the 0.1 - 125 microns and 125 - 2500 microns range, being made of Ca/P-based ceramic synthesis material using technologies for the impregnation/imbibition of porous supports (cellulose, polyurethane, resin), gel-casting, low pressure injection moulding.

- 9) The prosthetic device according to claim 8, characterised in that it is made of a ceramic material selected from the group consisting of: stoichiometric hydroxyapatite; non-stoichiometric hydroxyapatite: carbonated hydroxyapatite (mainly of type B); hydroxyapatite enriched with magnesium or fluoride or with strontium or sodium; carbonated hydroxyapatite enriched with magnesium; hydroxyapatite/ β tricalcium phosphate in proportions of 50% - 50%, 70% - 30%, 30% - 70%; alpha-tricalcium phosphate (α TCP); beta-tricalcium phosphate (β TCP); mixtures of alpha-tricalcium phosphate (α TCP) and beta-tricalcium phosphate (β TCP), the hydroxyapatite-based material which forms the subject matter of patent IT-1 307 292, and the hydroxyapatite-based material which forms the subject matter of patent EP-1 411 035 (and the

corresponding application for an Italian patent BO2002A000650).

- 10) The prosthetic device according to claim 8 or 9, characterised in that it constitutes a support (scaffold) for the attachment of cells and/or growth factors in order to create an osteoinductive effect and/or a support for "drug release" with which drugs and/or chemotherapeutic substances may be associated in medical or oncological therapies.